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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,824

Applicant(s)

SINDERBY ET AL.

Examiner

Joseph F. Weiss, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC # 103

1. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-19, 21-22, 24-31, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes (US 510783).

In regards to claim 24, Younes discloses a ventilatory having a first input (P sub mus) for receiving a first signal representative of inspiratory effort and which would have an amplitude, a second input (Volume feed back see figs 7 & 9 and supporting text) for receiving a second signal representative of volume and which would have a second amplitude, a calculator which is fully capable of calculating a relationship between the first and second signals (pre-programmed electronics 22) that by dint of having the same empirical input data and structure is thus fully capable of calculating the ratio in a manner that is falls within the ambit of neuro-ventilatory efficiency, and a control dependent on whether a present calculated value of said "neuro-ventilatory efficiency" is higher or lower than a past calculation of the "neuro-ventilatory efficiency/" by an amount exceeding a given threshold (pre-programmed electronics 22) to then increase or decrease the ventilatory assist level. (see graphs and supporting text of figs 1-7)

In regards to claim 25, Younes discloses a calculator comprising a divider responsive to the ratios at predetermined intervals and a control comprising a

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comparator & adder (see the calculations that are the basis of the invention and which are pre-programmed into the electronics 22, 01. 9 line 5 - col. 14. line 15, note prior claim rejection regarding the capabilities of the prior art to arrive at a value w/in the ambit of "neuro-ventilatory efficiency") wherein the adder is interposed between the comparator and the ventilatory assistance system.

In regards to claim 26, Younes discloses a calculator comprising a means for calculating said "neuro-ventilatory efficiency" relationship at predetermined intervals (note that the calculating means takes measurements over time and in relationship to respiratory events see col. 9 line 5- col. 14 line 15)

In regards to claim 27, the device of Younes discloses a calculator comprising a means for calculating said neuro-ventilatory efficiency' relationship that is fully capable of doing so at intervals when one of said first and second amplitudes reaches a predetermined level. (See col. 9 line 5- col. 14 line 15).

In regards to claim 28, Younes' adder comprises a means for adding and a means for subtracting that is fully capable of adding or subtracting a preset increment or decrement when the presently calculated neuro-ventilatory efficiency is lower or higher than the past calculated value when the difference exceeds a threshold for the increment or decrement.

In regards to claim 29, a signal representative of a lung volume is inherently indicative of a given lung volume, thus the second signal of Younes discloses a second signal that is indicative of a given lung volume.

In regards to claim 30, a signal representative of inspiratory effort is inherently

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indicative of a given inspiratory effort, thus the first signal of Younes discloses a first signal that is indicative of a given Lung volume.

In regards to claim 31, Younes discloses an alarm (col. 19 lines 27-32) that produces an alarm signal in response to deviations in signal data (note alarm activation in response to absence of a signal and also when lung pressure or volume is excessive) and hence would be fully capable of responding to deviations correlated to neuro-ventilatory efficiency when it exceeds a threshold amount.

In regards to claims 33 & 34, Younes discloses a means for expressing the first and second signals that is fully capable of expressing the signals as a mean, a median or a peak. (note electronics 22).

In regards to method claims 13-22, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 24-34.

3. Claims 20 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes as applied to claims 13 & 24 above, and further in view of Ernst (US 3961627).

In regards to claim 32, Younes substantially discloses the instant application's claimed invention, but does not explicitly disclose a manual adjustment system to add/subtract a preset increment/decrement. However, Ernst discloses such (9). The references are analogous since they are from the same field of endeavor, the respiratory would have been obvious to one of ordinary skill in the art to have taken the features of Ernst and used them with the device of Younes. The suggestion/motivation

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for doing so would have been to give the operator additional control over the device.

Therefore, at the time the instant application's invention was made, it would have would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claim 20, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claim 32.

4. Claims 23 & 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes as applied to claims 13 & 24 above, and further in view of Sackner (US 6015388).

Younes substantially discloses the instant application's claimed invention, but does not explicitly disclose deriving inspiratory effort from an EMG signal of at least one muscle of the subject. However, Sackner disclose such (Note use of diaphragm EMG in figs 1, EMGS of fig 2 and supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts.

At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sackner and used them with

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the device of Younes. The suggestion/motivation for doing so would have been to derive a more accurate indicator of inspiratory effort. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claim 23, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claim 34.

Response to Arguments

4. Applicant's arguments filed 20 Aug 04 have been fully considered but they are only partially persuasive.

In regards to the 35 USC 112 rejection, applicant's arguments & amendments are proper and responsive, and they resolve the issue, therefore the rejection with withdrawn.

In regards to the 35 USC 103 rejection, applicant's arguments are proper & responsive, but they are not persuasive for the following reasons:

First, It is noted that applicant does not expressly claim a calculation, just a capability to calculate, and a capability that does not evidence any sort of structural difference. Applicant does not argue that the Younes device does not have the same

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structure, just that it cannot perform the same calculation. Therefore one of ordinary skill in the respiratory art would have a reasonable basis to conclude that because the devices are the same structurally and are both in the same art field, respirators, that the device of Younes would be able to perform the same calculations, hence the arguments are not persuasive and Younes renders applicant's invention obvious.

In regards to applicant's assertion of what "neuro-ventilatory efficiency" means in the respiratory art, it is noted that no affidavit by a subject matter expert is in the file, no definition exists in the file that fully explicates the term, therefore the phrase is given its plain meaning. The term add no structure in its manner of claiming, thus we are left with a respirator that has two inputs, a calculator & a controller, just a different label to the ventilation parameter than Younes, thus Younes is fully capable of performing the functions of the device. Applicant needs to claim actual structural differences that relate to such terms that Younes does not possess to overcome the reject, to date applicant has not, hence the rejection stands.

In regards to the issue of what is respiratory effort, applicant admits on the record that the parameters of Younes are based upon respiratory muscles from the user, e.g. the diaphragm, this is the fundamental aspect of respiratory effort, hence applicants arguments amount to a mere difference without a distinction in terms of terminology.

In regards to applicant's arguments about the programmed circuits of Younes, it is noted that applicant admits on the record that the circuits are capable of being programmed, applicant has not set forth anything in his disclosure that the circuits need anything unique or specific to be programmed to make the intended result calculations

occur, hence the device of Younes has the same structure and hence capabilities as applicant's circuits which is all that applicant sets forth, a non-structural "capability."

Therefore, applicant's arguments are non-persuasive and accordingly, the rejection stands.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Weiss, Jr. whose telephone number is (571) 272-4805. The examiner can normally be reached on Monday through Friday from 8 am until 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JFW
3 Jan 05



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